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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,723	11/29/2005	Toshihiro Tanaka	P26633	1079

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GREENBLUM & BERNSTEIN, P.L.C.  
1950 ROLAND CLARKE PLACE  
RESTON, VA 20191

EXAMINER
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SALMON, KATHERINE D

ART UNIT	PAPER NUMBER
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1634

NOTIFICATION DATE	DELIVERY MODE
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08/08/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com  
pto@gbpatent.com

<b>Office Action Summary</b>	Application No. 10/523,723	Applicant(s) TANAKA ET AL.	
	Examiner Katherine Salmon	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-9 and 12, drawn to a method for determining an inflammatory disease comprising detecting at least one gene polymorphism existing in at least one gene from the group consisting of LT- $\alpha$ , IKBL, and BAT1.

Group II, claim(s) 10-11, drawn to a kit comprising at least one oligonucleotide.

Group III, claim(s) 13-14 and 16-17, drawn to a method for measuring the transcriptional activity of LT- $\alpha$ , IKBL, or BAT1 comprising introducing a gene fragment into a cell, culturing the cell, and analyzing the expression of the gene.

Group IV, claim(s) 15, drawn to a substance inhibiting the transcriptional activity of LT- $\alpha$ , IKBL, or BAT1.

Group V, claim(s) 18-19, drawn to a method for screening a transcriptional regulatory factor of comprising bring a gene fragment into contact with a sample and detecting binding of the fragment with the transcriptional regulatory factor.

Group VI, claim(s) 20-22, drawn to a method for evaluating ability to induce an adhesion molecule in a cell comprising introducing a gene fragment into a cell in which an adhesion molecule can be induced.

Group VII, claim(s) 23-25, 28- 32, drawn to a method of treating a inflammatory disease comprising suppressing the expression or activity of LT- $\alpha$ .

Group VIII, claim(s) 26-27, drawn to a therapeutic agent.

### **Further Restriction Requirement**

2. The groups listed above are subject to a FURTHER RESTRICTON Requirement

As discussed below, a further restriction requirement is being made such that applicant is required to further elect for **Groups I-V, a specific SNP or specific combination of SNPs from the group consisting of SEQ ID Nos 1-5.**

Group I comprises different groups of gene combinations wherein MPEP 1850 (R5) 13.3 states "The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim".

With regard to Groups I-V, the claims are drawn to "at least one" from the group comprising SEQ ID Nos 1-5. Therefore each different combination of a specific SEQ ID No or a specific combination of Seq ID Nos are separate inventive concepts.

For example, each of the following are combinations which are represented in each of the Groups presented above and each represents a different inventive concept:

- A. the combination of SEQ ID NO. 1 and 2
- B. the combination of SEQ ID NO. 3 and 4
- C. the combination of SEQ ID NO 5.

These combination of SEQ ID Nos do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the description fails to disclose that all of the SEQ ID Nos in each of the combinations share a common property or activity. While each combination of SEQ ID Nos might serve to detect its

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own respective full length DNA, due to the lack of sequence homology between each SEQ ID NO, one SEQ ID NO cannot be used to amplify the same region of DNA as another.

In the preceding example, the region which is amplified in Combination A is distinct from the regions amplified in Combinations B and C, and vice versa. Therefore each combination of SEQ ID Nos represents a different inventive concept

Moreover, since the polynucleotides are not homologous to each other, they fail to share a common structure, i.e., a significant structural element. The sugar-phosphate backbone cannot be considered a significant structural element, since all nucleic acid molecules share it. Therefore, the SEQ ID Nos do not share any significant structural element and cannot be considered as having the same or corresponding technical feature.

The mere fact that polynucleotide fragments (e.g. SEQ ID Nos) are derived from the same source (human genome) is not sufficient to meet the criteria for unity of invention. The polynucleotides fail to share a common property or activity and fail to share a common structure. Since neither of these two requirements is met, the group of polynucleotide molecules claimed does not meet the requirement of unity of invention.

Therefore applicant is required to elect a specific **SEQ ID NO** or a **SPECIFIC combination of SEQ ID Nos** from the group consisting of SEQ ID NO. 1-5.

3. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or

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corresponding special technical features. According to PCT Rule 13.2, unity of invention exists only when a shared same or corresponding special technical feature is a contribution over the prior art. The technical feature, which is shared by Groups I-VIII, is a polymorphism of an "A" at nucleotide 10 of Seq ID NO. 1 of the LT-alpha gene. Groups I-VIII do not share a special technical feature over the art because Genbank accession numbers AF129756 (October 28, 1999) teaches the partial sequence of the LTA gene (e.g. LT-alpha). Nucleotides 177760-177599 of GenBank Accession Number AF129756 are 100% identical to SEQ ID NO. 1 wherein at position 10 (e.g. 177769) there is an "A". The technical feature fails to make a contribution over the prior art; therefore, there is no special technical feature between Groups I-II.

4. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found

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allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Katherine Salmon  
Examiner  
Art Unit 1634

  
JEANINE A. GOLDBERG  
PRIMARY EXAMINER